

§ 35.636

10 CFR Ch. I (1–1–02 Edition)

of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);

(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;

(4) Viewing systems;

(5) Treatment room doors from inside and outside the treatment room; and

(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.

(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.

(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.636 Safety checks for teletherapy facilities.

(a) A licensee shall promptly check all systems listed in § 35.634(d) for proper function after each installation of a teletherapy source and after making

any change for which an amendment is required by § 35.606 (a) through (d).

(b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in § 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(c) A licensee shall retain for three years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988]

§ 35.641 Radiation surveys for teletherapy facilities.

(a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by § 35.606 (a) through (d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with § 35.51 of this part to verify that:

(1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 millirem per hour and 2 millirem per hour, respectively; and

(2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that:

(i) Radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in § 20.1201 of this chapter; and

(ii) Radiation dose rates in controlled or unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in § 20.1301 of this chapter.

(b) If the results of the surveys required in paragraph (a) of this section

Nuclear Regulatory Commission

§ 35.647

indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit:

(1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or

(2) Until the licensee has received a specific exemption pursuant to § 20.1301 of this chapter.

(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 63 FR 39483, July 23, 1998]

§ 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by § 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in § 20.1301 of this chapter, the licensee shall, before beginning the treatment program:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with § 20.1301 of this chapter.

(2) Perform the survey required by § 35.641 again; and

(3) Include in the report required by § 35.645 the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of this

section, and the results of the second survey.

(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under § 20.1301(c) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by § 20.1301(a) of this chapter. A licensee may not begin the treatment program until the license amendment has been issued.

[51 FR 36951, Oct. 16, 1986, as amended at 56 FR 23472, May 21, 1991; 58 FR 67660, Dec. 22, 1993; 63 FR 39483, July 23, 1998]

§ 35.645 Reports of teletherapy surveys, checks, tests, and measurements.

A licensee shall mail a copy of the records required in §§ 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in § 35.632, to the appropriate Commission Regional Office listed in § 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.

§ 35.647 Five-year inspection.

(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.